QUALITY MANAGEMENT TO ACHIEVE COMPLIANCE

entropy® software

Improve quality standards, internal control, external communications, and overall corporate performance with Entropy® Software

Overview

In today's business environment, expectations of transparency, real-time reporting, improved quality, and compliance assurance are becoming increasingly important for manufacturers and service providers in many industries around the world. Businesses live in a highly competitive world and need to stay ahead of the competition by delivering products & services to market on-time and with quality standards.

Manufacturers in the life sciences industry in particular are constantly pushing the boundaries of innovation and delivering more powerful products. Success is dependent on balancing business requirements:

- Introduce robust systems into business processes and ensure regulatory requirements are met;
- Differentiate over others in the market and obtain a competitive advantage;
- Improve quality tracking throughout the organization and increase customer satisfaction;
- Manage risk more effectively and enhance business performance;
- Streamline operations and improve financial performance;
- Attract investment and strengthen brand reputation.

The rapid pace of growth requires robust systems to ensure regulatory obligations and reporting requirements are being met. Success in the industry requires adherence to applicable regulations from FDA (including 21 CFR Part 820 and 21 CFR Part 11), and often requires meeting GMP as well as ISO standard requirements such as ISO 13485 / 9001, 14000 and OHSAS 18001.

Return on Investment

Organizations use Entropy Software to help manage and measure quality and compliance processes, improve reporting, better manage and mitigate risks, reduce costs, and streamline business processes. Entropy Software provides a quantifiable return on investment for its users.

Entropy Software's ability to comprehensively manage product documentation and produce actionable reports proves invaluable when working with regulatory agencies and certified bodies. For example, Entropy Software empowers companies to avoid FDA 483's and warning letters. Entropy software establishes a framework for creating and executing an enterprise's internal controls in order to reduce risk and improve regulatory compliance. By providing a consistent and comparable management framework across all sites, product introduction and certification, can be accelerated. In summary, Entropy Software enables more revenue by supporting quicker product introduction, while saving costs associated with regulatory oversight.

Throughout the Medical Devices product life cycle, expectations of transparency, real-time reporting, improved quality, and compliance assurance are becoming increasingly important.

bsi.

...making excellence a habit.

Ensure Speed-to-Market and Cut Compliance Costs with Entropy Software

Regulatory Compliance

Manufacturing companies in the medical devices industry face the complex task of continuing to meet regulatory requirements set forth by the FDA, GxP and reporting mandates, international device safety standards and marketing laws, and cross-industry compliance requirements. All of these requirements are stipulated by country-specific laws making compliance evolve from an isolated departmental initiative to an enterprise-level risk management challenge.

Entropy Software offers a comprehensive suite of quality and compliance management tools that serves the unique needs of healthcare product manufacturers. Entropy Software enables companies to take a process-based approach to quality and compliance management. It creates real-time visibility into the quality and document management process and establishes key performance indicators by which objectives can be met.

By improving operational efficiencies in compliance processes and quality systems, Entropy Software lowers the cost of regulatory compliance and creates a transparent environment that proactively identifies, tracks, and resolves quality and compliance related issues.

Efficient Product Rollout

Quality issues can delay a product launch, and costing a medical device manufacturers revenue and market share resulting in dissatisfaction. Entropy Software enables an enterprise-wide quality program, by streamlining data collection and eliminating inaccurate or out-of-date information. By entering data only once, organizations can reduce errors and duplication while increasing global access to reliable and consistent information. Easy and effective reporting options provide quality managers, product managers, and top executives with exceptional insight to the business.

Business System Integration

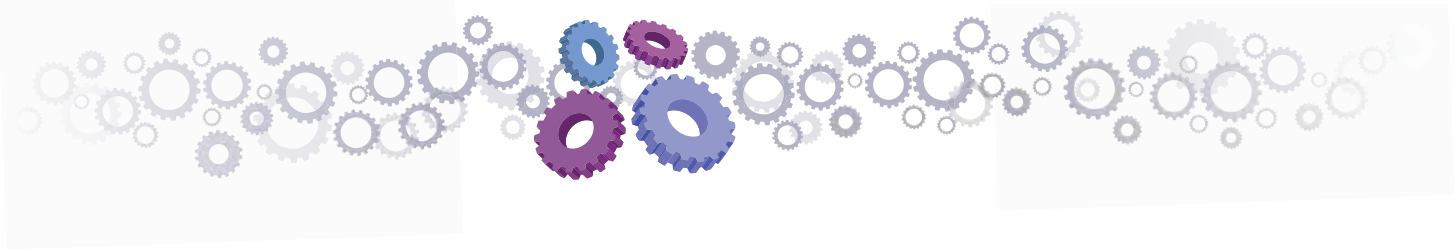
As programs are implemented in an organization to improve quality processes, organizations recognize the need to integrate multiple systems that aid and support them. As an integrated risk and compliance management solution, Entropy Software reduces the need for multiple systems through an exceptionally intuitive, adaptive and user-friendly interface.

Mitigating Brand Risk Across Complex Value Chains

Consistency of quality has emerged as a differentiator for organizations in the medical devices industry. But enterprises are challenged with overcoming the legacy of loosely integrated technology and business processes. Enterprises are forced to create a common model that bridges together organizational quality realization processes and bridging the gaps between quality planning and execution. As a single, integrated risk and compliance management solution, Entropy Software enables organizations to assess and investigate quality events, which can help organizations to reduce overlap and/or address process gaps across the business. With the ability to instantly locate, evaluate, and manage material risks anywhere within the business, Entropy Software helps protect the organization's brand and enhance its reputation.

Entropy Software delivers comprehensive tools to achieve:

- **CAPA: Correction and Preventative Action**
- **P&PC: Production and Process Controls**
- **QSR: Quality System Requirements**
- **DES: Design Controls**
- **DOC: Document Controls**



Feature Capabilities

entropy® software

Products and Services
- Product realization planning and customer-specific processes
- Design and development planning, inputs, outputs, validation and review
- Tracking for control of production and service provision
- Purchasing information, verification of purchased product and effectiveness of processes

Quality Control
- Tools for quality issue identification, failure mode and effects analysis (FMEA), and risk assessment
- Standard and administrable assessment methodologies
- Issue details and categories

Reporting
- Detailed site reports for all tools
- Extensive category and query filter options
- Organization-wide roll-up reporting

Non-Conformance Reporting
- Raise and document non-conformances
- Automatically record non-conformances from audits
- Link action plans to rectify non-conformances

Equipment Inventory
- Track all equipment
- Historical maintenance and calibration records
- Reminders for inspection and calibration reviews

Action Plans
- Create action plans and allocate responsibility
- Reminders for completion dates and reviews
- Define task dependencies and milestones
- Escalation through management structure

Document Management
- Framework for all system documentation
- Automated version control
- Customizable access, approval and reporting privileges
- E-signature capability

Audit
- Schedule and conduct audits
- Customize audit checklists, guidance and scoring
- Run detailed, summary and site-ranking reports
- Create action plans from audit results

Objectives and Targets
- Set, manage and report objectives and targets
- Reminders for completion dates and reviews
- Assign responsibilities to individuals/roles and teams

Management Review
- Schedule management reviews
- Document agendas, attendance and minutes
- Automatically create action plans and tasks

Training
- Document training courses and procedures
- Identify training needs by role, process or activity
- Automatic reminders for pending training
- Requirements tracked for training competency

Legislations and other requirements
- Store details of legislation, permits and codes of practice
- Relate records to regulatory requirements, processes and activities
- Reminders for reporting requirements

Entropy Software reduces the need for multiple systems through an exceptionally intuitive and user-friendly interface.

Entropy® Software for Medical Device Manufacturers

Reduce risk, aid conformance, and maintain effective corporate performance worldwide.

BSI/USA/274/MS/0511/E

About Entropy Software

Entropy Software is a web-based solution providing a technology framework that allows companies to effectively manage their Governance, Risk and Compliance (GRC) activities. Entropy Software helps businesses continuously improve control, assurance, and accountability; reduce risks, incidents, liability, and cost; and protect and enhance brand value and reputation. Designed and developed to meet recognized international standards, Entropy Software provides a risk management and compliance system that is certifiable and auditable against the requirements of the standards such as ISO, OHSAS, BS, and others. For more details on Entropy Software visit **www.bsi-entropy.com**.

How can we help?

Next Steps

Whether you are improving an established system or embarking on a new investment, Entropy Software can be tailored to meet your needs. BSI can provide implementation services to understand your strategic objectives and show you how your business could benefit from the Entropy Software. We will use your data to find the solution that is right for you and tailored to your requirements.

www.bsiamerica.com/needsanalysis

About BSI

BSI is a global independent business services organization which enables businesses, governments and other organizations to increase profits and market access, and to enhance reputation with its standards-based solutions and assurance services. From its origins as the world's first National Standards Body, BSI draws upon over 100 years' experience to partner with 66,000 organizations in 147 countries from its 50 offices. Today, through its independence, innovation and integrity, BSI continues to improve the lives of millions by raising standards worldwide. To learn more about BSI, please visit **www.bsiamerica.com**

BSI SERVICES SUMMARY

- Information and guidance
- Standards and publications
- Training – understanding, implementation, lead auditor
- Management systems – gap analysis, second party audits, assessment, certification, continual assessment
- Business improvement tools and software

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